

REMARKS

This is a Response to the final Office Action mailed on December 8, 2009. A petition for a one month extension of time is submitted with this Response. The Commissioner is hereby authorized to charge \$130.00 for the petition for extension of time and any additional fees that may be required or credit any overpayment to the Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3714652-509 on the account statement.

Claims 35, 45, 48-52 and 57-64 are pending in the application. Claims 1-34, 36-44, 46-47, 53-56 and 65-68 were previously canceled. In the Office Action, Claims 35, 45, 48-52 and 57-64 are rejected under 35 U.S.C. §112 and Claims 35, 45, 48-52 and 57-64 are rejected under 35 U.S.C. §103. For at least the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

35 U.S.C. §112 Rejection

In the Office Action, Claims 35, 45, 48-52 and 57-64 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More specifically, the Examiner asserts that the terms "acidifier" and "fish oil" are unclear. Applicants respectfully disagree and submit that the scope of the terms "acidifier" and "fish oil" are clear in view of the knowledge of the skilled artisan and the teachings of the specification.

The skilled artisan understands the term "acidifier" to be a compound that can increase the pH of another substance. The specification further discloses that examples of suitable acidifiers are citric acid and lactic acids. See specification, page 8, lines 11-12. In addition, the term "fish oil" is commonly known to be an oil derived from the tissues of oily fish. As a result, the metes and bounds of the terms "acidifier" and "fish oil" are clear to the skilled artisan. Based on at least these noted reasons, Applicants believe that the pending claims fully comply with 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112 be withdrawn.

First 35 U.S.C. §103 Rejection

In the Office Action, Claims 35, 45, 48-52 and 57-64 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,471,999 to Couzy et al. ("*Couzy*") in view of U.S. Patent No. 6,524,619 to Pearson et al. ("*Pearson*") and further in view of "Micronutrient status in patients with gastrointestinal disease" to Simpson et al. ("*Simpson*"), U.S. Patent No. 6,228,367 to Watson ("*Watson*"), U.S. Patent No. 6,160,007 to DeMichele et al. ("*DeMichele*") (erroneously listed as U.S. 6,610,007) and WO 01/62280 to Margolin et al. ("*Margolin*"). Applicants respectfully traverse the rejection for at least the reasons set forth below.

Independent Claims 35, 52 and 61 recite, in part, an edible composition comprising a pancreatic function-promoter comprising an acidifier, a liver function-promoter comprising taurine ranging between about 0.1% and about 1% by weight of the edible composition on a dry matter basis, and an intestinal mucosa function-promoter comprising fish oil ranging between about 0.1% and 20% by weight of the edible composition on a dry matter basis. The edible composition can improve or maintain or promote a cat's lipid absorption capacity, which increases the absorption capacity of Vitamin E. In contrast, Applicants respectfully submit that even if combined the cited references fail to disclose or suggest each and every element of the present claims.

Vitamin E is a fat-soluble vitamin that is absorbed only with long chain fatty acids. A defect in either the absorption or digestion of lipid can therefore lead to deficiencies in this and other vitamins, due to their binding with unabsorbed fatty acids (Simpson, K W and Michel, K E. Micronutrient status in patients with gastrointestinal disease. Proceedings ACVIM, Denver, Colo., pp. 651-653, 2001). Hence, a pet with low lipid digestibility is susceptible to several potential nutritional deficiencies, which can compromise its health.

Studies on senior cat nutrition have shown that a significant number of older pets--such as those above the age of 9 years--exhibit a decreased capacity to digest fat. Several scientific publications have likewise reported an age-related decrease in lipid digestibility in cats (Burkholder. W J. Age-related changes to nutritional requirements and digestive function in adult dogs and cats. JAVMA, Vol 215, No. 5, Sep. 1, 1999; Nicholson A, Watson A D J. Mercer J R. Fat malassimilation in three cats. Australian Veterinary Journal, Vol. 66, No. 4, April, 1989;

Peachey S E, Dawson J M, Harper E J. The effects of aging on nutrient digestibility by cats fed beef tallow, sunflower oil or olive oil enriched diets). There can be any of a number of pathologies that can lead to poor digestibility of lipids. Malabsorption and maldigestion can occur from almost any diffuse disease of the intestine, from exocrine pancreatic insufficiency or from unknown causes. In the case of cats, pancreatitis occurs at a prevalence rate of about 0.15% to 3.5% and may account for some cases of poor fat digestibility. Diffuse intestinal diseases, such as intestinal lymphoma, small intestinal bacterial overgrowth, inflammatory bowel disease and liver disease, may also lead to reduced nutrient absorption in the small intestine.

“One way for a patent applicant to rebut a prima facie case of obviousness is to make a showing of ‘unexpected results,’ i.e., to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected.” *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995). Applicants have surprisingly found that an edible composition comprising an acidifier, taurine ranging between about 0.1% and about 1% by weight of the edible composition, and fish oil ranging between about 0.1% and 20% by weight of the edible composition improved the fat digestibility of the edible composition. As further shown by FIG. 1 of the specification, there is a direct correlation between fat digestibility and enhancement of the serum Vitamin E level. In other words, a composition that increases fat digestibility also increases the absorption capacity of Vitamin E by the body of the animal. See specification, page 13, lines 20-25. This can reduce the effects of Vitamin E deficiency in a pet.

Applicants submit a Declaration under 37 C.F.R. §1.132 (“*Declaration*” attached hereto as Attachment 1) that demonstrates the unexpected results of administering an edible composition comprising an acidifier, taurine, and fish oil to a cat. As supported by the *Declaration*, a group of 20 cats with low fat digestibility (i.e., less than 80%) was fed diets to determine if there was an improvement in fat digestibility in old cats fed different diets containing combinations of pancreatic function promoters, liver function promoters, and intestinal mucosa function promoters, a “wet” diet (Diet A), a “dry” diet, (Diet B). It should be noted that the *Declaration* describes a more detailed version of the study of Example 1 in the specification.

The diets in the study contained a pancreatic function promoter (Diet A + citric acid), a liver function promoter (Diet A + taurine), an intestinal mucosa function promoter (Diet A + fish oil in the form of omega 3 oils), and a combination of the promoters (Diet C) were formulated and fed to cats using the procedure similar to that given in Example 1 of the above-identified patent application. The citric acid in the diets was in an amount of approximately 0.1% by weight. The taurine in the diets was in an amount of approximately 0.8% by weight. The fish oil in the diets was in an amount of approximately 3% by weight.

As supported by the *Declaration*, the control diets (Diet A and Diet B) showed a fat digestibility of about 61% and 63%, respectively, as shown in Figure 1 of the *Declaration*. There was no significant difference between fat digestibility of a wet diet and a dry diet. This confirms that the digestibility of wet and dry diets is substantially the same and that diet is not a factor in evaluating digestibility. Diet A + citric acid, Diet A + taurine, and Diet A + fish oil showed an increase in fat digestibility of 6.6%, 6.1% and 5.5% respectively when compared to the control diets. However, surprisingly, the combination of the three promoters showed a much more pronounced affect on fat digestibility. The combination (Diet C) showed an increase in fat digestibility of 17.5%.

As supported by the *Declaration*, in old cats with reduced fat digestibility (<80%), the presence of a single pancreatic function promoter (acidifier), a single liver function promoter (taurine), or a single intestinal mucosa function promoter (omega 3 oils) improved the level of fat digestibility (around 5.5 to 6.6%). However, none of these diets increased the level of fat digestibility above 80%, the level considered as normal. When the inventors provided the same old cats with a diet that contains a combination of a pancreatic function promoter (acidifier), a liver function promoter (taurine), and an intestinal mucosa function promoter (omega 3 oils), the improvement in the level of fat digestibility is more dramatic (around 17.5%). Only with this diet did the old cats reach a level of fat digestibility that was considered normal (above 80%). This is a dramatic effect; not even in young healthy cats can fat digestibility be 100%. Moreover, no digestive system is 100% efficient (every meal produces some fecal content).

As supported by the *Declaration*, the results are surprising and unexpected when the percentage of cats that showed an increase in fat digestibility is analyzed as shown in Figure 2 of the *Declaration*. The percent of cats that had an improved fat digestibility when administered the

promoters in combination was 90%, as compared to the 67% to 75% for the promoters alone. About 20% more cats will have increased fat digestibility if administered a combination of promoters than if administered one of the promoters alone. Thus, one critical discovery is that the number of cats that benefit from a combination of a pancreatic function promoter (acidifier), a liver function promoter (taurine), and an intestinal mucosa function promoter (omega 3 oils) is much greater than the number of cats that benefit from a single promoter. Figure 2 shows that 90% of the cats improved their fat digestibility, versus only 75% when fed a diet with a single pancreatic function promoter (acidifier), 67 % with a single liver function promoter (Taurine), or 67% with a single intestinal mucosa function promoter (omega 3 oils).

As supported by the *Declaration*, the decrease in fat digestibility in old cats is a complex problem that involves a decrease in pancreatic function, liver function, and/or intestinal mucosal function. In most cases, as is frequent with old age, there is not a clear and consistent malfunction, but a concomitant and interrupted decrease of multiple organ efficiency or malfunction. The inventors made a critical discovery in that the number of cats that benefit from an edible composition including a combination of a pancreatic function promoter (acidifier), a liver function promoter (taurine), and an intestinal mucosa function promoter (omega 3 oils) is much greater than the number of cats that benefit from a single promoter. The beneficial effects of the edible composition lead to an increase in fat digestibility in the cat that also correlates to an increase in the absorption capacity of Vitamin E by the cat.

In contrast to the present claims and the *Declaration*, Applicants respectfully submit that *Couzy, Pearson, Simpson, Watson, DeMichele* and *Margolin* alone or in combination fail to disclose or suggest a liver function-promoter comprising taurine ranging between about 0.1% and about 1% by weight of the edible composition on a dry matter basis as required independent Claims 35, 52 and 61. Applications also respectfully submit that *Couzy, Pearson, Simpson, Watson, DeMichele* and *Margolin* fail to disclose or suggest the specific combination of the acidifier, taurine and fish oil in a single edible composition for improving or maintaining absorption of vitamin E in a cat as recited by independent Claims 35, 52 and 61.

Though *Couzy* mentions use of taurine, *Couzy* never teaches a level or range for taurine. *Pearson* is said to disclose that taurine can be used to enhance absorption of a drug. *Watson* and *DeMichele* fail to teach the use of or even mention any taurine. The Patent Office relies on

DeMichele for a disclosure of fish oil and *Simpson* and *Margolin* to arguably teach lipid assimilation. Nevertheless, these references fail to disclose or suggest the claimed range of the liver function-promoter and specific combination of components in accordance with Claims 35, 52 and 61.

In sum, *Couzy*, *Pearson*, *Simpson*, *Watson*, *DeMichele* and *Margolin* alone or in combination fail to disclose or suggest each and every element of independent Claims 35, 52 and 61. Moreover, the cited references fails to even recognize the advantages, unexpected benefits and/or properties of the edible composition and methods of feeding the composition to a cat in accordance with the present claims. Consequently, independent Claims 35, 52 and 61, along with the claims that depend from Claims 35, 52 and 61, are novel and non-obvious over the cited references.

Second 35 U.S.C. §103 Rejection

In the Office Action, Claims 35, 45, 48-52 and 57-64 are rejected under 35 U.S.C. §103(a) as being unpatentable over WO 02/15719 to *Fuchs et al.* ("*Fuchs*") in view of U.S. *Pearson* and further in view of *Simpson*, *Watson*, *DeMichele* and *Margolin*. Applicants respectfully traverse the rejection for at least the reasons set forth below.

Applicants respectfully submit that *Fuchs*, *Pearson*, *Simpson*, *Watson*, *DeMichele* and *Margolin* alone or in combination fail to disclose or suggest a liver function-promoter comprising taurine ranging between about 0.1% and about 1% by weight of the edible composition on a dry matter basis as required independent Claims 35, 52 and 61. Applications also respectfully submit that *Fuchs*, *Pearson*, *Simpson*, *Watson*, *DeMichele* and *Margolin* fail to disclose or suggest the specific combination of the acidifier, taurine and fish oil in a single edible composition for improving or maintaining absorption of vitamin E in a cat as recited by independent Claims 35, 52 and 61.

Fuchs teaches use of emulsifiers and taurine, but without any usage levels. *Pearson* is said to disclose that taurine can be used to enhance absorption of a drug. *Watson* and *DeMichele* fail to teach the use of or even mention any taurine. The Patent Office relies on *DeMichele* for a disclosure of fish oil and *Simpson* and *Margolin* to arguably teach lipid assimilation.

Nevertheless, these references fail to disclose or suggest the claimed range of the liver function-promoter and specific combination of components in accordance with Claims 35, 52 and 61.

In sum, *Fuchs, Pearson, Simpson, Watson, DeMichele* and *Margolin* alone or in combination fail to disclose or suggest each and every element of independent Claims 35, 52 and 61. Moreover, the cited references fails to even recognize the advantages, unexpected benefits and/or properties of the edible composition and methods of feeding the composition to a cat in accordance with the present claims. Consequently, independent Claims 35, 52 and 61, along with the claims that depend from Claims 35, 52 and 61, are novel and non-obvious over the cited references.

Accordingly, Applicants respectfully request that the obviousness rejections with respect to the pending claims be reconsidered and the rejections be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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